

REMARKS

Claims 5, 7, 8, 72 and 73 are pending. Claims 1-4 and 9-69 are cancelled as being drawn to a non-elected invention. Claims 6, 70-73 are currently cancelled. Claims 5 and 7 are currently amended. New claim 74 has been added.

Support for the amendments to claims 5 and 7 is found throughout the specification and in particular at Example 20.

Applicants submit that no new matter has been added as a result of this amendment.

Applicants acknowledge that the rejection of claims 5, 7, 8 and 70 under 35 U.S.C. 102(b) in view of Van Ooigen et al. (U.S. 6,022,846) is withdrawn.

Applicants also acknowledge that the rejection of claims 5, 7, 8 and 70 under 35 U.S.C. 103(a) in view of Howard et al. (WO 97/10347) is withdrawn.

Applicants also acknowledge that the rejection of claim 72 under 35 U.S.C. 103(a) in view of Van Ooigen in view of Schwoebel et al. (Journal of Biological Chemistry, 266: 7214-7219, 1991) and Walmsley et al. (Current Opinion in Biotechnology, 11: 126-129, 2000) is withdrawn.

Applicants also acknowledge that the rejection of claim 72 is rejected under 35 U.S.C. 103(a) in view of Howard et al. (WO 97/10347) in view of Bliel et al. (WO 98/00440) is withdrawn.

Objections

In response to the objection to claim 72 for allegedly failing to further limit the subject matter of the claim from which it depends, Applicants have cancelled claim 72.

Rejection of Claim 72 Under 35 U.S.C. §112, fourth

In response to the rejection of claim 72 for allegedly failing to further limit the subject matter of the claim from which it depends, Applicants have cancelled claim 72 thereby rendering the rejection moot.

Rejection of Claims Under 35 U.S.C. §103(a)

Claims 5, 7, 8 and 72 are rejected under 35 U.S.C. 103(a) in view of Howard et al. (WO 97/10347) in view of Bliel (WO 98/00440) and further in view of Russell-Jones (J. of Controlled Release (2000) Vol. 65; pp. 49-54).

Claim 73 is rejected under 35 U.S.C. 103(a) in view of in view of Howard, in view of Bliel and further in view of Russell-Jones and further in view of Mowat (Immunology Letters (1999) Vol. 65; pp. 133-140).

Applicants respectfully traverse the rejections.

Claims 72 and 73 have been cancelled.

Claim 5 has been amended to recite “a stable dry homogenate of a transgenic plant expressing a heterologous contraceptive protein comprising ZP3 and *E. coli* enterotoxin subunit B, further comprising an antigen or antibody, and further comprising a mucosal targeting protein, in combination with a saponin adjuvant, wherein said stable dry homogenate is prepared by a method comprising:

- a. obtaining either intact or partitioned transgenic plant material;
- b. dehydrating said transgenic plant material;
- c. mixing said transgenic plant material into a homogenate either before or after said dehydrating step,

thereby producing a stable dry homogenate of a transgenic plant expressing a heterologous protein, wherein administration of said homogenate in combination with said saponin adjuvant to an animal induces an immune response.”

Claim 7 has been amended to recite “a stable dry homogenate comprising a dehydrated transgenic plant material containing a transgenic contraceptive protein comprising ZP3 and *E. coli* enterotoxin subunit B, and further comprising a mucosal

targeting protein, in combination with a saponin adjuvant, wherein administration of said homogenate in combination with said saponin adjuvant to an animal induces an immune response.”

None of Howard et al., Bliel and Russell-Jones, either alone or in combination teach or suggest “a stable dry homogenate of a transgenic plant expressing a heterologous contraceptive protein comprising ZP3 and *E. coli* enterotoxin subunit B, further comprising an antigen or antibody, and further comprising a mucosal targeting protein, in combination with a saponin adjuvant, wherein said stable dry homogenate is prepared by a method comprising:

- a. obtaining either intact or partitioned transgenic plant material;
- b. dehydrating said transgenic plant material;
- c. mixing said transgenic plant material into a homogenate either before or after said dehydrating step,

thereby producing a stable dry homogenate of a transgenic plant expressing a heterologous protein, wherein administration of said homogenate in combination with said saponin adjuvant to an animal induces an immune response” as required by claim 5.

None of Howard et al., Bliel and Russell-Jones, either alone or in combination teach or suggest “a stable dry homogenate comprising a dehydrated transgenic plant material containing a transgenic contraceptive protein comprising ZP3 and *E. coli* enterotoxin subunit B, and further comprising a mucosal targeting protein, in combination with a saponin adjuvant, wherein administration of said homogenate in combination with said saponin adjuvant to an animal induces an immune response” as required by claim 7

For at least the reasons set forth herein, Applicants respectfully submit that the Examiner has failed to establish a *prima facie* case of obviousness under the requirements of 35 U.S.C. § 103(a). To establish a *prima facie* case of obviousness, three basic criteria must be met. First, there must be some suggestion or **motivation, either in the references themselves or in the knowledge generally available to one of ordinary skill in the art, to modify the reference or to combine reference teachings** (*In re Vaeck*, 947 F.2d 488, 20 USPQ2d 1438 (Fed. Cir. 1991)). Second, there must be a

In view of all of the above, Applicants respectfully request withdrawal and reconsideration of the rejection.

Respectfully submitted,

By /Elizabeth Spar
Elizabeth Spar
Registration No.: 45,123
Customer No. 21874
EDWARDS ANGELL PALMER & DODGE
LLP
P.O. Box 55874
Boston, Massachusetts 02205
(617) 439-4444
Attorneys/Agents For Applicant